MAY 1979
VOLUME 68 NUMBER 5

JOURNAL OF PHARMACEUTICAL SCIENCES

The *Journal of Pharmaceutical Sciences* (ISSN 0022-3549) is published monthly by the American Pharmaceutical Association (APhA) at 2215 Constitution Ave., N.W., Washington, DC 20037. Second-class postage paid at Washington, D.C., and at additional mailing office.

Offices—Editorial, Advertising, and Subscription: 2215 Constitution Ave., N.W., Washington, DC 20037. Printing: 20th & Northampton Streets, Easton, PA 18042.

Annual Subscriptions—United States and foreign, industrial and government institutions $50, educational institutions $50, individuals *for personal use only* $30; single copies $5. All foreign subscriptions add $5 for postage. Subscription rates are subject to change without notice. Members of APhA may elect to receive the *Journal of Pharmaceutical Sciences* as a part of their annual $70 (foreign $75) APhA membership dues.

Claims—Missing numbers will not be supplied if dues or subscriptions are in arrears for more than 60 days or if claims are received more than 60 days after the date of the issue, or if loss was due to failure to give notice of change of address. APhA cannot accept responsibility for foreign delivery when its records indicate shipment has been made.

Change of Address—Members and subscribers should notify at once both the Post Office and APhA of any change of address.

Photocopying—The code at the foot of the first page of an article indicates that APhA has granted permission for copying of the article beyond the limits permitted by Sections 107 and 108 of the U.S. Copyright Law provided that the copier sends the per copy fee stated in the code to the Copyright Clearance Center, Inc., P.O. Box 8891, Boston, MA 02114. Copies may be made for personal or internal use only and not for general distribution.

Microfilm—Available from University Microfilms International, 300 N. Zeeb Road, Ann Arbor, MI 48106.

BUREAUCRATIC OVERKILL

Those who have had the good fortune of being able to read newspapers or periodicals in which columnist James J. Kilpatrick's writings appear are familiar with his uncanny ability to discuss rules and regulations that smack of "overkill." He is able to write about such measures in a manner that—while entertaining and amusing—leads the reader persuasively along a pathway to the conclusion that the regulation is absurd, ridiculous, and even beyond belief.

Recently, we read his column concerning a particular regulation that previously had our casual support. However, by the time we finished reviewing Mr. Kilpatrick's analysis and commentary, we were squirming in embarrassment for the poor agency official who had innocently promulgated the requirement.

Mr. Kilpatrick's remarkable ability to blow away all the extraneous aspects and to expose the utter absurdity of the underlying requirement came to mind recently in connection with one of the ancillary provisions of the Food and Drug Administration's revised and expanded Good Manufacturing Practices regulations.

This massive tome, which was released last fall, constitutes FDA's effort to codify who may manufacture drugs and how such manufacturing facilities shall be outfitted, organized, staffed, and operated. While opinions may vary, we happen to feel that this basic objective is a good thing. Hence, our immediate, general inclination is to support these reorganized and expanded GMP regulations. We suspect that this attitude is shared by most people in the pharmaceutical field including the majority of our readers.

But tucked away in this huge document is a provision that, in our opinion at least, constitutes the regulatory "overkill" that would cause Mr. Kilpatrick's ire to rise and his typewriter to hum.

Specifically, John W. West, a pharmacist at a Holland, Michigan, community hospital, has called attention to FDA's declaration that hospitals that do packaging for unit dose dispensing must now comply with the full GMP regulations. He notes with astonishment and disbelief that, "*These regulations are the same as those required of the pharmaceutical manufacturing industry. They mandate extensive stability testing, in-process inspections, a separate quality control unit,* etc. *Unlike industry, the community hospital pharmacy simply does not have these extensive control facilities.*"

Now, if the hospital pharmacy were engaged in drug manufacturing in the usual and conventional sense, then there would be no quarrel about FDA's sweeping application of these requirements. But a unit dose dispensing system simply enables the pharmacist to dispense the medication in a convenient and ready-to-administer form. For example, individual tablets or capsules are dispensed in a single packet bearing the name of the drug, its strength, its control number, and any other pertinent information.

Unit dose drug distribution systems have been encouraged by APhA, and other professional pharmacy organizations, because their adoption and use have been shown to reduce the incidence of medication errors, decrease the cost of delivering medication to the patient, and facilitate in drug identification, control, and storage. The system has other obvious advantages from the standpoint of minimizing contamination and maintaining drug purity and potency.

A goodly number of drugs can be obtained directly from the manufacturer in unit dose package form. But many other drugs are not so available. To fill this gap, hospital pharmacists use a simple packaging machine to produce unit dose packets in the hospital pharmacy.

It is regarding this operation that the long arm of the FDA has reached in and grabbed on grounds that it is "manufacturing" and that it eliminates the pharmacy's exemption from having to comply with the complete GMP requirements which apply to full scale drug manufacturing plants.

The regulations in the *Federal Register* discussed strip-packaging and related types of repackaging by "pharmacies and hospitals in particular," and in this context concluded by saying:

> "*When a hospital or pharmacy is engaged in drug repackaging or relabeling operations that are beyond the usual conduct of dispensing or selling drugs at retail, however, the exemptions of the act cease to apply; the establishment is required to register and is subject to regular inspections under section 704 of the act. Furthermore, appropriate current good manufacturing practice must be complied with.*"

High quality pharmaceutical service is something that should be encouraged. Regrettably, this ill-conceived regulation will discourage such quality service by forcing institutional pharmacies to abandon the unit dose concept.